

**REMARKS**

The Examiner provides a number of rejections; we list them here in the order in which they are addressed.

I. Claims 27-29, 31, 33-41, 43 and 44 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly not enabling.

II. Claims 27-29, 31, 33-41, 43 and 44 are rejected under 35 USC § 112 second paragraph as allegedly being indefinite.

III. Claims 27-29, 31, 33-41, 43 and 44 are rejected under 35 USC § 112 second paragraph as allegedly being incomplete.

IV. Claims 27-29, 31, 33, 34, 36-41 and 44 are rejected under 35 USC § 102(e) as allegedly being anticipated by United States Patent No. 6,813,518.

V. Claims 35 and 43 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kupper *et al.*

**I. The Claims Comply With The Written Description Requirement**

The Examiner states that:

Having the implantable device configured to deliver the pacing burst to discriminate VT from SVT is critical or essential to the practice of the invention, but not included in the claim(s) ...

*Office Action pg. 3.* The Applicants disagree. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claims 27 and 37 to again recite previous elements (b) and (c). These amendments are made not to

acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

The Examiner is respectfully requested to withdraw the present rejection.

## **II. The Claims Are Definite**

The Applicants submit that this rejection is now moot based upon the above claim amendments made for other reasons. The Applicants respectfully request that the Examiner withdraw the present rejection.

## **III. The Claims Are Complete**

The Examiner states that:

The omitted elements are: Having the implantable device configured to deliver the pacing burst to discriminate VT from SVT ...

*Office Action pg 3.* The Applicants disagree and submit that this rejection is now moot based upon the above claim amendments made for other reasons. The Applicants respectfully request that the Examiner withdraw the present rejection.

## **IV. The Claims Are Novel**

The Examiner states that:

Kupper discloses a pacemaker/defibrillator ... [that] ... necessarily does determine the earliest arriving electrical signal and the location of origin (atrium or ventricle) ... since following therapy it waits to sense a ventricular or atrial event ...

*Office Action pg 4.* The Applicants disagree Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claims 27 and 37 to further clarify that the device is configured to "diagnose an origin of an arrhythmia" using an 'earliest arriving electrical signal' following 'a blanking period':

Figure 4A shows the last three pacing beats induced by a burst of 400 msec square wave depolarizations (STIM) triggering a blanking period (blanking period

from last ATP stimulation to dashed vertical line). After the blanking period, ventricular activity is recorded (see RVA d; arrow) prior to atrial activity (see MAP d; arrow). Similarly, Figure 4B also shows first arriving ventricular activity except that the pacing beats were induced by 350 msec stimulus (STIM) and atrial activation is recorded on HRA d (see arrow) and I-IRA p leads and compared with ventricular data recorded on RVA p and RVA d leads (see arrows).

Ventricular tachycardia is diagnosed as persistent in both tracings because the ventricular electrical signal appears prior to the atrial electrical signal ... Figure 5 shows the last two pacing beats induced by a 350 msec stimulus (STIM) triggering a blanking period (blanking period from last ATP stimulation to dashed vertical line). After the blanking period, atrial activity is recorded (see HRA d or HRA p; arrows) prior to ventricular activity (RVA p or RVA d; arrow).

Supraventricular tachycardia is diagnosed as persistent because the atria electrical signal appears prior to the ventricular electrical signal ... Figure 6 shows the last four pacing beats induced by a 360 msec stimulus (STIM) triggering a blanking period (blanking period from last ATP stimulation to dashed vertical line). After the blanking period, atrial activity (HRA d), ventricle activity (RVA p) and His bundle activity (HIS d) all appear simultaneously.

Atrioventricular nodal reentrant tachycardia is, therefore, diagnosed.

*Applicants' Specification pg 24 ln 24 - pg 25 ln 18, and Figures 4, 5 and 6.*

Consequently, Claims 27 and 37 are further clarified to recite that the "origin of cardiac arrhythmia" include ventricular tachycardia, supraventricular tachycardia and atrioventricular nodal reentrant tachycardia. These amendments are made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

Kupper et al. does not teach a device configured with 'a blanking period' (i.e., a refractory period) for diagnosing an origin of tachyarrhythmias such as supraventricular tachycardia (i.e., atria tachyarrhythmia), ventricular tachycardia and/or atrioventricular nodal reentrant tachycardia. Kupper et al. discloses a device where the 'refractory' and/or 'blinking' periods are used for either operational control or represents an unusable timeframe:

... digital timers and counters establish the overall escape interval of the IMD 10 as well as various refractory, blanking and other timing windows for controlling the operation of peripheral components disposed within input/output circuit 54.

*Kupper col 6 ln 21-25 [emphasis added], and*

In the event an atrial or ventricular tachyarrhythmia is detected and an anti-tachyarrhythmia pacing regimen is desired, appropriate timing intervals for controlling generation of anti-tachyarrhythmia pacing therapies are loaded from microprocessor 51 into the pacer timing and control circuitry 63, to control the operation of the escape interval counters therein and to define refractory periods during which detection of R-waves and P-waves is ineffective to restart the escape interval counters.

*Kupper col 11 ln 1 - 9* [emphasis added]. Unlike the Applicant's claimed embodiment, Kupper et al. does not contemplate detecting the first arriving electrical signal 'after the blanking period' to diagnose either a ventricular tachycardia or an atrial tachycardia. Specially, Kupper et al. provides a device configured to terminate atrial fibrillation:

The present invention is therefore directed to providing a method and system for terminating atrial fibrillation by inducing a ventricular extra-systole through combipolar pacing.

*Kupper col 3 ln 8-11.* Further, Kupper et al. is unable to distinguish between the presence of atrial and/or ventricular tachyarrhythmia's:

Detection of atrial or ventricular tachyarrhythmias, as employed in the present invention, may correspond to any of the various tachyarrhythmia detection algorithms presently known in the art. For example, the presence of an atrial or ventricular tachyarrhythmia may be confirmed by detecting a sustained series of short R-R or P-P intervals or an average rate indicative of tachyarrhythmia or an unbroken series of short R-R or P-P intervals.

*Kupper col 10 ln 38-45* [emphasis added]. Clearly, Kupper et al. uses identical characteristics to identify either an atrial or ventricular tachyarrhythmia, such that they cannot be respectively diagnosed.

Consequently, the Applicants respectfully request that the Examiner withdraw the pending rejection.

### III. Claims 35 and 43 Are Not Obvious Over Kupper

The Examiner states that:

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the IMD as taught by Kupper ...

*Office Action pg 4 bridging pg 5.* The Applicants disagree because the Examiner is referring to dependent claims. Because the respective independent claims (i.e., Claims 27 and 37, respectively) have not been rejected as obvious, the dependent claims are non-obvious as well:

Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious.

*In re Fine, 837 F.2d 1071, 1076, 5 USPQ2d 1596 (Fed. Cir. 1988).* Consequently, the Applicants respectfully requests that the Examiner withdraw the present rejection.

### CONCLUSION

Based on the arguments provided above, Applicants believe that the Claims 27-29, 31 and 33-44 are in condition for allowance. Should the Examiner believe a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned at 781-828-9870.

Respectfully submitted,

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